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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,668	07/08/2003	Antonello Covacci	CHIR-0337	6533

7590  
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Intellectual Property  
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EXAMINER
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DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

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02/05/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/615,668	<b>Applicant(s)</b> COVACCI ET AL.	
	<b>Examiner</b> S. Devi, Ph.D.	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 38-40, 44-46, 48-50, 54, 57, 58, 62, 64, 65 and 70-72 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 38-40, 44-46, 48-50, 54, 57, 58, 62, 65 and 70-72 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 08/471,491.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>120408 &amp; 102808</u>                                       | 6) <input type="checkbox"/> Other: _____                          |

### **Request for Continued Examination**

1) A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicants' submission filed on 10/27/08 has been entered.

### **Applicants' Amendment**

2) Acknowledgment is made of Applicants' amendment filed 10/27/08 in response to the final Office Action mailed 05/29/08.

### **Previous Office Action Vacated**

3) The Office Action mailed 01/23/09 is hereby vacated and is replaced with the instant Office Action.

### **Status of Claims**

4) Claims 38, 44, 49, 50, 54, 57, 64, 65, 70 and 71 have been amended via the amendment filed 10/27/08.

Claims 56, 59 and 68 have been canceled via the amendment filed 10/27/08.

Upon further consideration, the search has been extended to the polynucleotide species encoding the amino acid sequence of SEQ ID NO: 27, and claims 71 and 72 have been fully examined.

Claims 38-40, 44-46, 48-50, 54, 57, 58, 62, 64, 65 and 70-72 are under examination.

### **Information Disclosure Statements**

5) Acknowledgment is made of Applicants' information disclosure statement filed 10/27/08 and 12/04/08. The information referred to therein has been considered and a signed copy is attached to this Office Action.

### **Terminal Disclaimer**

6) Acknowledgment is made of Applicants' terminal disclaimer filed 08/26/08 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of the US Patent 6,090,611.

### **Prior Citation of References**

**7)** The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

### **Objection(s) Moot**

**8)** The objection to the specification made in paragraph 8 of the Office Action mailed 05/29/08 is moot in light of Applicants' cancellation of claim 68.

### **Rejection(s) Moot**

**9)** The rejection of claims 59 and 68 made in paragraph 10 of the Office Action mailed 04/09/07, made/maintained in paragraph 20 of the Office Action mailed 11/16/07 and made/maintained in paragraph 13 of the Office Action mailed 05/29/08 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 6 and 7 of US patent 6,090,611 (Applicants' IDS), is moot in light of Applicants' cancellation of the claims.

**10)** The provisional rejection of claims 59 and 68 made in paragraph 9 of the Office Action mailed 04/09/07, made/maintained in paragraph 20 of the Office Action mailed 11/16/07, and made/maintained in paragraph 12 of the Office Action mailed 05/29/08 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 39 and 40 of the co-pending application 11/580,632, is moot in light of Applicants' cancellation of the claims.

**11)** The rejection of claims 56 and 68 made in paragraph 18 of the Office Action mailed 05/29/08 under 35 U.S.C. § 112, first paragraph, as containing new matter, is moot in light of Applicants' cancellation of the claim.

**12)** The rejection of claims 56, 59 and 68 made in paragraph 20(d) of the Office Action mailed 05/29/08 under 35 U.S.C § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.

**13)** The rejection of claims 68 and 56 made in paragraph 22 of the Office Action mailed 05/29/08 under 35 U.S.C. § 102(b) as being anticipated by Covacci *et al.* (*PNAS* 90: 5791-5795, June 1993, of record), is moot in light of Applicants' cancellation of the claims.

**14)** The rejection of claims 68 and 56 made in paragraph 23 of the Office Action mailed 05/29/08 under 35 U.S.C. § 102(b) as being anticipated by Peterson *et al.* (*Nature* 354: 369-373, 1991, already of record), is moot in light of Applicants' cancellation of the claims.

### **Rejection(s) Withdrawn**

**15)** The rejection of claims 38-40, 44, 49, 50, 62, 65 and 70 made in paragraph 10 of the Office Action mailed 04/09/07, made/maintained in paragraph 20 of the Office Action mailed 11/16/07 and made/maintained in paragraph 13 of the Office Action mailed 05/29/08 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 6 and 7 of US patent 6,090,611 (Applicants' IDS), is withdrawn in light of Applicants' submission of a terminal disclaimer disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of the US Patent 6,090,611.

**16)** The rejection of claims 44-46 made in paragraph 23 of the Office Action mailed 05/29/08 under 35 U.S.C. § 102(b) as being anticipated by Peterson *et al.* (*Nature* 354: 369-373, 1991, already of record), is withdrawn. A new rejection is set forth below to address the claims as amended.

Applicants contend that claim 44 has been amended as indicated. Applicants submit that it has not been established that the Peterson reference teaches an isolated polynucleotide encoding a *Helicobacter pylori* CAI antigen as presently claimed. However, unlike the polynucleotide claimed in claim 38, wherein the polynucleotide is required to be all or a part of SEQ ID NO: 4, the isolated polynucleotide claimed in the amended independent claim 44 is not required to be from SEQ ID NO: 4. The only requirement of the isolated polynucleotide of claim 44 as claimed currently is that it is required to encode the EPIYA sequence, i.e., SEQ ID NO: 10. The isolated polynucleotide taught by Peterson *et al.* encodes an at least five amino acid-long polypeptide comprising the amino acid sequence of EPIYA (i.e., the instantly recited SEQ ID NO: 10). Since the prior art EPIYA sequence is structurally the same as the instantly recited

SEQ ID NO: 10 encoded by the claimed polynucleotide, it is expected to necessarily serve inherently as a *H. pylori* CAI antigen immunologically identifiable with the instantly recited SEQ ID NO: 5. See the new rejection set forth below over the teachings of Peterson *et al.*

**17)** The rejection of claims 44 and the dependent claims 45, 46, 49, 50, 54 and 57 made in paragraph 18 of the Office Action mailed 05/29/08 under 35 U.S.C. § 112, first paragraph, as containing new matter, is withdrawn in light of Applicants' amendment to the claims and/or the base claim. A new rejection is set forth below to address the claims as amended.

**18)** The rejection of claim 38 made in paragraph 20(a) of the Office Action mailed 05/29/08 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

**19)** The rejection of claim 48 made in paragraph 20(b) of the Office Action mailed 05/29/08 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the base claim.

**20)** The rejection of claim 44 made in paragraph 20(c) of the Office Action mailed 05/29/08 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

**21)** The rejection of claims 39, 40, 44-46, 48-50, 54, 57, 58, 62, 64, 65 and 70 made in paragraph 20(d) of the Office Action mailed 05/29/08 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the base claim.

### **Rejection(s) Maintained**

**22)** The provisional rejection of claims 38-40, 44, 49, 50, 54, 62, 64 and 65 made in paragraph 9 of the Office Action mailed 04/09/07, made/maintained in paragraph 20 of the Office Action mailed 11/16/07, and made/maintained in paragraph 12 of the Office Action mailed 05/29/08 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 39 and 40 of the co-pending application 11/580,632, is maintained for reasons set forth therein. Applicants ask that the rejection be held in abeyance pending an indication of allowable subject matter.

Claims 71 and 72 are now added to this rejection since the polynucleotide claimed in these claims is encompassed within the scope of claims 39 and 40 of the co-pending application.

**23)** The rejection of claims 44-46, 49, 50, 54 and 57 made in paragraph 22 of the Office Action mailed 05/29/08 under 35 U.S.C. § 102(b) as being anticipated by Covacci *et al.* (*PNAS* 90: 5791-5795, June 1993, of record), is maintained for the reasons set forth therein and herein below.

Claim 71 is now added to this rejection since the polynucleotide taught by Covacci *et al.* encodes an amino acid sequence comprising SEQ ID NO: 27.

Applicants contend that claim 44 has been amended as indicated. Applicants state that the claims are fully supported by Figure 4 of PCT/EP93/00472 filed 03/02/1993 and therefore the Covacci reference is not prior art to the present claims.

Applicants' argument has been fully considered, but is not persuasive. As explained in the paragraph below, instant claims continue to include new matter, and therefore are granted the effective filing date of the instant application. Therefore, the Covacci reference still qualifies as prior art.

### **Rejection(s) under 35 U.S.C. § 112, First Paragraph (New Matter)**

**24)** The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**25)** Claim 44 and the dependent claims 45, 46, 49, 50, 54 and 57 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 44, as amended, is drawn to '[a]n isolated polynucleotide encoding a *Helicobacter pylori* CAI antigen, wherein said *Helicobacter pylori* CAI antigen comprises the amino acid sequence of SEQ ID NO: 10' comprises the amino acid sequence of SEQ ID NO: 10.'

Applicants state that exemplary support for the claims is located in Figure 4 of the specification.

However, unlike the polynucleotide claimed in claim 38, wherein the polynucleotide is required to be all or a part of SEQ ID NO: 4, the SEQ ID NO: 10-encoding isolated polynucleotide claimed in the amended independent claim 44 is not required to be from SEQ ID NO: 4.

Therefore, the claimed polynucleotide encompasses a polynucleotide or a part of a polynucleotide other than SEQ ID NO: 4 depicted in Figure 4 of the instant specification. As set forth previously, Figure 4 is exclusively supportive of SEQ ID NO: 4 comprising a nucleotide sequence therein that encodes the amino acid sequence of SEQ ID NO: 10, wherein the nucleotide bases outside of the sequence that encodes SEQ ID NO: 10 are from SEQ ID NO: 4. Figure 4 is not supportive of a generic polynucleotide of any microbial or non-microbial origin comprising nucleotide sequence encoding the amino acid sequence of SEQ ID NO: 10, but describes specifically the *cai* gene species of the G39 strain of *H. pylori* wherein the gene species is limited to SEQ ID NO: 4, but not any generic gene. New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed by pointing to specific lines and pages, for the new limitations, or alternatively, remove the new matter from the claim(s). Applicants should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06.

### **Rejection(s) under 35 U.S.C. § 112, Second Paragraph**

**26)** The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

**27)** Claims 38-40, 44-46, 48-50, 54, 57, 58, 62, 64, 65, 70 and 71 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter, which Applicants regard as the invention.

(a) Claims 38, 44, 49, 50, 54, 57, 64, 65, 70 and 71 are vague and indefinite in the use of the abbreviated language 'CAI' in the claim. It is suggested that the abbreviation be recited as a full terminology at first occurrence in the base claim, with its abbreviated recitation retained in parentheses.



(b) Claims 39, 40, 48, 58, 62, 64, 65, 70 and 71, which depend directly or indirectly from claim 38, and claims 45, 46, 49, 50, 54 and 57, which depend directly or indirectly from claim 44, are rejected as being indefinite, because of the indefiniteness or vagueness, identified above in the base claim.

### **Rejection(s) under 35 U.S.C. § 102**

**28)** The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**29)** Claims 44-46 are rejected under 35 U.S.C. § 102(b) as being anticipated by Peterson *et al.* (*Nature* 354: 369-373, 1991, of record) as evidenced by Stein *et al.* (*Mol. Microbiol.* 43: 971-980, 2002 – Applicants' IDS).

Peterson *et al.* taught an isolated polynucleotide encoding an at least five amino acid-long polypeptide comprising the amino acid sequence of EPIYA (i.e., the instantly recited SEQ ID NO: 10) and *E. coli* cells overexpressing the same. See right column of page 369 and Figure 1. Since the prior art EPIYA sequence is structurally the same as the instantly recited SEQ ID NO: 10 encoded by the claimed polynucleotide, it is expected to necessarily serve inherently as a *H. pylori* CAI antigen immunologically identifiable with the instantly recited SEQ ID NO: 5. That the prior art EPIYA sequence is the same the Applicants' *H. pylori* CAI antigen, EPIYA or SEQ ID NO: 10, is inherent from the teachings of Peterson *et al.* in light of what is well known in the art. For example, Stein *et al.* illustrate that EPIYA motif is an essential part of the CagA protein of *H. pylori*. See title and abstract of Stein *et al.*

Claims 44-46 are anticipated by Peterson *et al.* The reference of Stein *et al.* is **not** used as a secondary reference in combination with Peterson *et al.*, but rather is used to show that every element of the claimed subject matter is disclosed by Peterson *et al.* with the unrecited limitation(s) being inherent in view of what is known in the art as explained above. See *In re Samour* 197 USPQ 1 (CCPA 1978).

### **Remarks**

**30)** Claims 38-40, 44-46, 48-50, 54, 57, 58, 62, 64, 65 and 70-72 stand rejected.

**31)** Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Central Fax number, (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

**32)** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

**33)** Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Robert Mondesi, can be reached on (571) 272-0956.

/S. Devi/  
Primary Examiner  
AU 1645

January, 2009